APLAN WELL APLAN WELL ENTERPRISE CO.,LTD K112734 P1&2
No.1, Aly. 81, Ln. 2, Sec. 1, Zhongxing Rd., Dali Dist., Taichung City 412, Taiwan (R.O.C.)
TEL : (04)2492-0550 FAX : (04)2496-7052 E-mail:aplan.easy@msa.hinet.net

II. 510(K) Summary of Safety and Effectiveness

APR 2 4 2012

(Per 21 CFR 807.92)

2.1. General Information Establishment

- Manufacturer: **APLAN Well Enterprise Co., Ltd.**
- Address: No. 1, Alley 81, Lane 2, Sec. 1, Zhongxing Rd., Dali Dist., Taichung City, Taiwan, R.O.C.
- Owner Number: **3008496213**
- Contact Person: Dr. Jen, Ke-Min E-mail: ceirs.jen@msa.hinet.net
  886-3-5208829 (Tel); 886-3-5209783 (Fax)
  Address: No.58, Fu Chiun Street, Hsin Chu City, 30067, Taiwan, ROC
- Date Prepared: August 22, 2011

Device

- **Proprietary Name:** A.V. Fistula Needle Set for Single Use
- **Common Name:** Fistula Needle
- **Classification Name:** Needle, Fistula, non-implantable less than 30 days
- **Product Code:** **FIE** Class II, 876.5540

2.2. Safety and Effectiveness Information

- **Predicate Device:**
  Claim of Substantial Equivalence (SE) is made to JMS North America Corp. A.V. Fistula Needle Set for Single Use **(K990470)**
- **Device Description:**
  A.V. Fistula Needle Set is a single-use fistula needle which is inserted for temporary cannulation (non-implantable, less than 30 days) to vascular access for extracorporeal blood treatment. The device consists of a needle that is attached to wings, a flexible tube and a luer lock connector.
- **Performance Data:**
  A.V. Fistula Needle Set for Single Use completed the relevant test including:
  1) ASTM F750-87: Standard practice for evaluating material extracts by systemic injection in the mouse;
  2) ISO 10993-1: Biological evaluation of medical devices, Part 11.Tests for System Toxicity;
  3) ISO 10993-4: Biological evaluation of medical devices, Part 1. Evaluation and testing with a risk management process;
  4) ISO 10993-5: Biological evaluation of medical devices, Part 5.Tests for in vitro cytotoxicity;

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5) ISO 10993-7: Biological evaluation of medical devices, Part 7. Ethylene oxide sterilization residuals;
6) ISO 10993-10: Biological evaluation of medical devices, Part 10.Tests for Irritation & sensitization;
7) ISO 10993-11: Biological evaluation of medical devices, Part 11.Tests for System Toxicity;
8) ISO 11135-1: Sterilization of health care Ethylene oxide, Part 1. validation and routine control of a sterilization process;
9) Tensile Force Test and compared to the predicate device.

- **Intended Use:**

  The A.V. Fistula Needle Set is intended for temporary cannulation (non-implantable, less than 30 days) to vascular access for extracorporeal blood treatment. The device is intended for single use only.

- **Substantial Equivalence (SE)**

  A claim of substantial equivalence is made to JMS A.V. Fistula Needle Set for Single Use **(K990470).** Both of them have the sane indications for use, same materials used in the blood contact components, and adopt same fundamental scientific technology as the predicate device. Bench testing was conducted to verify that the APLAN A.V. Fistula Needle Set for Single Use performs as intended to be a safe and effective medical device. Thus they are substantially equivalent.

Dr. Jen, Ke-Min
official correspondent for
APLAN Well Enterprise Co., Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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% Dr. Jen, Ke-Min
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No.58, Fu Chiun Street
HSIN CHU CITY 30067
TAIWAN, R.O.C.

APR 2 4 2012

Re: K112734
Trade/Device Name: A.V. Fistula Needle Set for Single Use,
Nominal Capacity: 15G, 16G, 17G,
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: FIE
Dated: January 31, 2012
Received: February 9, 2012

Dear Dr. Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510 (K) Number (If Known): K112734

Device Name: *A.V. Fistula Needle Set for Single Use, Nominal Capacity: 15G, 16G, 17G,*

Indications for Use:

The A.V. Fistula Needle Set is intended for temporary cannulation (non-implantable, less than 30 days) to vascular access for extracorporeal blood treatment. The device is intended for single use only.

Prescription Use √ AND/OR Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112734